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(54) Throw-away breath sample device.

(57) A throw-away apparatus for taking and holding breath samples is particularly appropriate for determining carbon monoxide and, therefore, indirectly carboxyhemoglobin in blood, and comprises an elongate hollow body (10) defining a chamber therein; an inlet at one end (16) of the body, the inlet defining a mouthpiece for the apparatus; an outlet at the end (14) of the body opposite the inlet; a valve orifice (20) adjacent the inlet; one-way valve means (22) for closing the orifice (20); the valve means being biased to allow passage of breath sample from the inlet to the outlet; and expandable sample container means (12) in flow communication with the outlet for receiving breath samples therefrom. The apparatus is configured to allow for the taking of a single breath sample which may provide two or three separate and subsequent readings on an analyzer instrument. The sample may be held and maintained for a period of time prior to the subsequent analysis. The device is of simplified construction of inexpensive materials, making it particularly appropriate for mass production techniques. It may include a separate disposable mouthpiece (30) so that the device may be used several times prior to discarding.

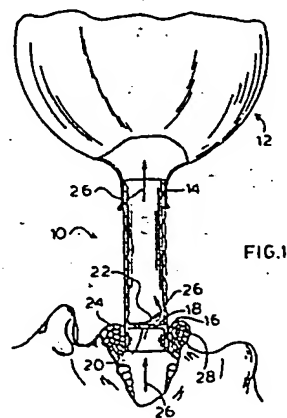


FIG.1

THROW-AWAY BREATH SAMPLE DEVICEBACKGROUND AND STATEMENT OF THE INVENTION

A throw-away device is provided for taking breath samples. More particularly, the invention is directed to a throw-away device which will take a breath sample and hold it for a subsequent connection to an analyzer instrument for testing the sample. The device is of simplified construction which may be easily manufactured of inexpensive materials so that it may be used only once or several times prior to discarding. The device is particularly appropriate for use in determining carboxyhemoglobin in blood.

It is now well known and recognized by public health authorities that a relationship exists between the carboxyhemoglobin content of human blood, and the carbon monoxide content of alveolar air in the breath of humans. Alveolar air is the air contained in the deepest part of the lung. It is obtained by causing a person to inhale deeply, to hold the inhaled breath for a short while, and to cause that person to slowly exhale while catching or collecting the very last portion of the air with the lungs emptied. The device of the invention is arranged to take the sample of air exhaled, and to hold it for subsequent application to instrumentation for reading the breath sample. By doing so, the carbon monoxide content of the sample is determined, and the carboxyhemoglobin (COHb) content of the blood of the person from whom the sample is taken may be determined, rapidly, according to the formula.

$$\% \text{ COHb} = \sqrt{109.08 + 7.6 \text{CO}_A} \cdot 11.89$$

-2-

A patient, using the 20 second breath-holding technique, blows into the instrument of the invention which collects and holds the sample for subsequent application to an instrument, as described below, for  
5 an analysis of the carbon monoxide content. This is converted into the percent of carboxyhemoglobin according to this well established relationship.

The arrangement of the invention here allows for taking samples of within the range of 500-800 ccs.  
10 (cubic centimeters). The sample is held for subsequent connection to an instrument for reading the sample taken. Since only 200ccs are needed to take a reading on the instrumentation, two to three separate subsequent readings may be taken from a single sample  
15 exhaled from a patient. Thus, an immediate reading can be taken of a patient in only a few seconds, rather than waiting for a blood test result. This is particularly important for people exposed to high carbon monoxide concentrations such as those involved  
20 in firefighting, for example. The device is particularly appropriate for use by paramedics or emergency room personnel for determining and preventing hypoxic stress in such people exposed to high carbon monoxide concentrations.

25 The apparatus of the invention involves a device which is particularly appropriate for use in emergency situations because a breath sample can be taken under unusual and difficult conditions, and the sample held for subsequent application to an  
30 instrument. Thus, a paramedic may take a sample from an individual and the sample is held until the

-3-

paramedic is able to unpack an instrument which may be included in his gear for a subsequent reading. It is not necessary that a difficult and involved instrument must be connected to or held adjacent to the person from whom the sample is being taken. Once the device containing the sample is connected to the instrumentation, an arrangement is provided for such a connection, in accordance with this invention, which provides an automatic sample release of the sample, and a controlled feeding of the sample to the instrumentation so that the appropriate quantity of air sample is fed at a constant rate to the instrument for the reading. The proposed apparatus is particularly suited for mass screening as performed by health authorities, in that it allows collecting samples by several technicians who, after mass collection will introduce, one by one the identified samples into the associated reading instrument.

Other objects and advantages of this invention will be apparent from the following description, the accompanying drawings and the appended claims.

#### DESCRIPTION OF THE DRAWINGS

Fig. 1 is a partial verticle sectional view of a device illustrating the invention applied to the lips of a patient from who a sample is being taken;

Fig. 2 is a partial verticle sectional view of the device of Fig. 1 with an additional separate mouthpiece being utilized; and

Fig. 3 is a partial verticle sectional view of the device of Fig. 1 attached to the sample collector and valve release block of the invention

-4-

which serves to feed a sample to instrumentation at a constant rate for a reading.

#### DETAILED DESCRIPTION OF THE INVENTION

Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, a breath collector tube 10 is shown in Fig. 1 having a balloon 12 fitted on the end 14 thereof for receiving a breath sample. As shown in Fig. 1, the lips 24 of the mouth 28 of a patient receives the end 16 of the breath collector tube 10. The patient blows in the direction of arrows 26 the breath sample, as described above, which is the last portion of an inhaled and held sample of breath which passes according to arrows 26 into balloon 12 through an orifice 20. The orifice 20 is positioned in valve seat 18, and is controlled by a valve flap 22, shown in its open position in Fig. 1. The valve flap 22, as will be understood, opens to the position shown in Fig. 1, under the force of the sample blown in the direction of arrows 26 by the patient through the breath collector tube.

For sanitary reasons, the breath collector tube may have a separate disposable mouthpiece 30, as shown in Fig. 2, which mouthpiece may be removed from the breath collector tube 10 after each sample taking, and discarded for sanitary reasons. Under extreme conditions of contagion or in order to comply with local laws concerning contamination, it may be necessary to discard the entire apparatus, after the taking and measuring of each individual sample in breath collector tube 10 received in the balloon 12.

-5-

Since the collector arrangement is of simplified construction and may be comprised of inexpensive materials, discarding after each use is not a serious problem in use. The balloon may contain 500-800 cc of air in the form of a breath sample taken from a patient. The sample, once taken, may be held in the device shown in Figs. 1 or 2 until such time as the device is connected to instrumentation for taking a reading of the sample.

The arrangement for receiving and reading the sample taken is shown in Fig. 3. In Fig. 3 a sample collector and valve release block 34 is shown having a bore 36 in the top surface thereof. Bore 36 may be of a diameter just slightly larger than the outer diameter of breath collector tube 10 for receiving end 16 of breath collector tube 10 in a sealing engagement therein. An O-ring seal 38 is incorporated into bore 36 for maintaining this sealing engagement between bore 36 and the breath collector tube 10. Positioned in the bottom of bore 36 is a fixed pin 40, which is held in place in a counterbore 41 in the bottom surface of bore 36. Pin 10 extends upwardly into bore 36 for engaging the valve flap 22 when the breath collector tube 10 is received in bore 36. Thus, valve 22 is opened automatically when the breath collector tube 10 is received in bore 36.

As can be seen in Fig. 3, a passage 44 is formed in valve release block 34 for carrying a sample in the direction of arrows 32 from the balloon 12, containing the sample, through the breath collector tube 10, through orifice 20 when valve 22 is

-6-

opened. In the bottom of block 34 at the end of passage 44 opposite bore 36 is a threaded bore 42 for receiving a threaded fitting 46. Fitting 46 also includes a passage 48 which cooperates with passage 5 44 in block 34 for providing flow communication from bore 36 to a flexible tube 54. The end 58 of tube 54 is fitted over the fitting 46 for containing the sample and directing the sample in the direction of arrows 56 toward an instrument for reading the sample. 10 The instrument may be, for example, a portable carbon monoxide monitor ECOLYZER<sup>R</sup> Model Number 210 or 211 manufactured by Energetics Science Division of Becton Dickinson and Company, Six Skyline Drive, Hawthorne, New York 10532. Positioned in 15 flexible tube 54 may be a flow restrictor 50 with a controlled orifice 52 so as to maintain a controlled continuous rate of flow of the sample in the direction of arrows 56 to the instrument for the reading of the sample.

20 As discussed above, since balloon 12 may have a capacity of 500-800cc, a sample may provide two or three separate readings in the attached instrument. That is, the Model 210 or 211 ECOLYZER<sup>R</sup> requires only 200cc to obtain a reading within the 25 range of 30 seconds to one minute. Thus, three separate readings from a single sample may be taken within a very short period of time in order, for example, for a paramedic to obtain information concerning possible overexposure to carbon monoxide 30 in an emergency situation. It will be appreciated, that such rapid determinations can also be made by hospital personnel so that they do not need to wait for a testing of a blood sample prior to making a

-7-

determination of such exposure. It will be appreciated, that it is within the purview of this invention that passage 44 in block 34 or passage 48 in fitting 46 may be sized and configured to provide a  
5 restricted controlled flow rather than the use of a separate flow restrictor 50 as shown in Fig. 3.

Thus, as will be appreciated from the foregoing, there is provided in accordance with this invention a simple inexpensive throw-away light-  
10 weight type device for obtaining breath samples for determining the carbon monoxide content of the sample. Moreover, the arrangement is so simple and light-weight that it may be utilized in very difficult situations requiring emergency readings and so  
15 forth. The apparatus of the invention is arranged to take and hold a sample until it can be properly attached to instrumentation for a reading. Thus, it is not necessary for the user to be burdened with instruments at the site where the sample is being  
20 taken.

The breath collector tube of the invention may be comprised of metal, plastic or cardboard. Preferably, the throw-away disposable mouthpiece 30  
25 will be comprised of cardboard which may be used and thrown away. The collector tube, preferably, has a length of about three to six inches and a diameter of about one-half inch. The valve release block 34 may vary in size, as will be appreciated as long as it is able to accommodate a bore 36, pin 40 and counterbore  
30 41, and a separate bore 42 as shown in Fig. 3. Preferably, bore 36 has a length of about three times the diameter of tube 10 and a diameter of just slightly larger than the diameter of tube 10.

-8-

Orifice 52 is of a size which will allow for a specified quantity of a sample of about 200cc to pass therethrough within a period of about 30 seconds. As stated above, passage 44 or passage 48 may be sized and configured to provide this restricted and controlled flow. Moreover, the orifice 20 in valve seat 18 may also be arranged to provide a controlled restricted flow. While a flapper valve of a soft flexible material, such as 22 is shown and described, it will be understood that other configurations of one-way valves may be utilized for receiving and holding a breath sample until such time as the sample is to be taken and measured. Such valves include, for example, spring biased valves.

While the forms of apparatus herein described constitute preferred embodiments of the invention, it is to be understood that the invention is not limited to these precise forms of apparatus, and that changes may be made therein without departing from the scope of the invention, which ~~is defined in the appended claims.~~

## CLAIMS

1. A throw-away apparatus for taking and holding breath samples, characterized by

- (a) an elongate hollow body (10) defining a chamber therein;
- (b) an inlet at one end (16) of the body, the inlet defining a mouthpiece for the apparatus;
- (c) an outlet at the end (14) of the body opposite the inlet;
- (d) a valve orifice (20) adjacent the inlet;
- (e) one-way valve means (22) for closing the orifice (20);
- (f) the valve means being biased to allow passage of breath sample from the inlet to the outlet; and
- (g) expandable sample container means (12) in flow communication with the outlet for receiving breath samples therefrom.

2. An apparatus according to claim 1, further characterized by a hollow elongate throw-away mouthpiece (30) for the breath sample apparatus, the mouthpiece having first and second open ends at least one of which is of a size for receiving in press-fit engagement the inlet end (16) of the body inlet.

3. An apparatus according to claim 2, further characterized in that the body (10) is tubular; the mouthpiece is tubular; and the internal diameter of the mouthpiece is large enough to receive the tubular inlet end of the body in pressfit engagement.

4. An apparatus according to claim 1, 2 or 3, further characterized in that the one-way valve means is a resilient flap valve (22) mounted with one side edge connected to the body and the opposite edge mounted for movement between a closed position closing the orifice (20) to an open position.

5. An apparatus according to any preceding claim, further characterized in that the expandable sample container means (12) is a balloon.

6. An apparatus according to any preceding claim, further characterized by a breath sample collector therefor, the breath sample collector comprising

(a) a collector body (34);

(b) a sample collector body inlet for receiving the breath sample body inlet;

(c) abutment means (40) in the sample collector body inlet for engaging and biasing the one-way valve means to an open position;

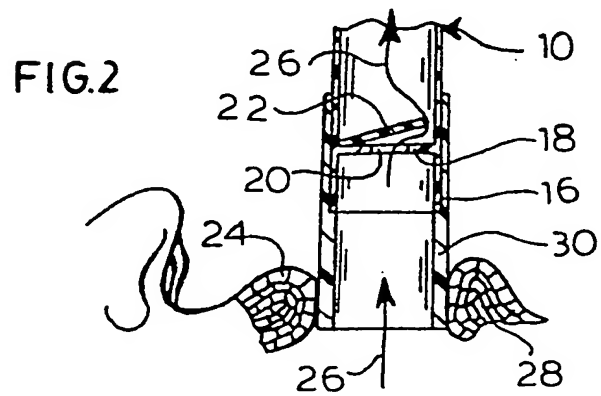
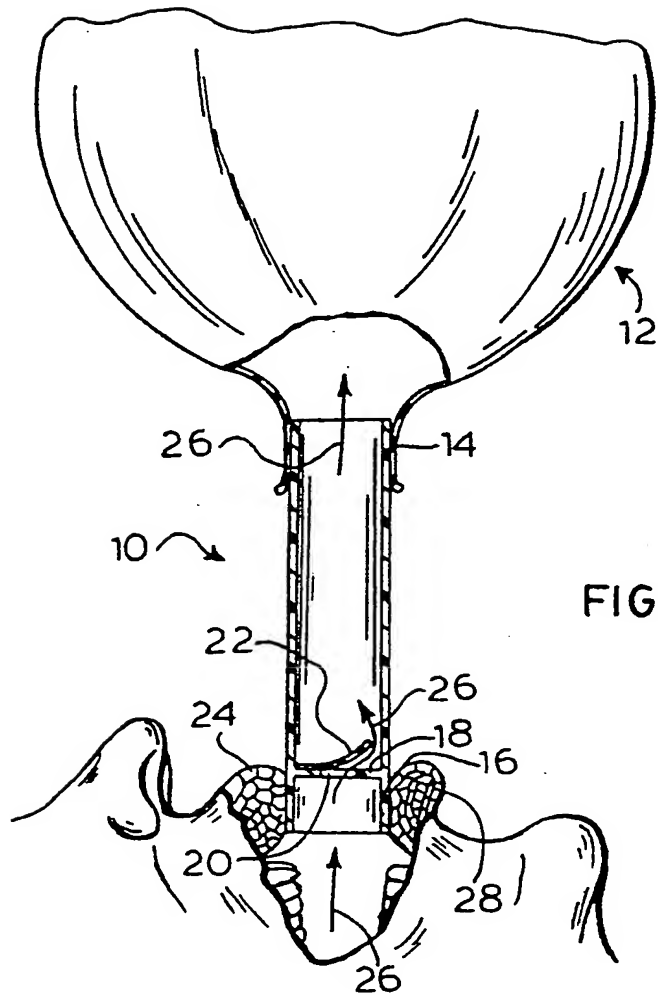
(d) an outlet in the collector body;

(e) means connected to the outlet for conveying a breath sample therefrom to a breath sample testing instrument;  
(f) means (44) providing flow communication from the sample collector body inlet to the breath sample conveying means, and  
(g) flow restrictor means (50) in the flow communication means for controlling the rate of breath sample flow therethrough.

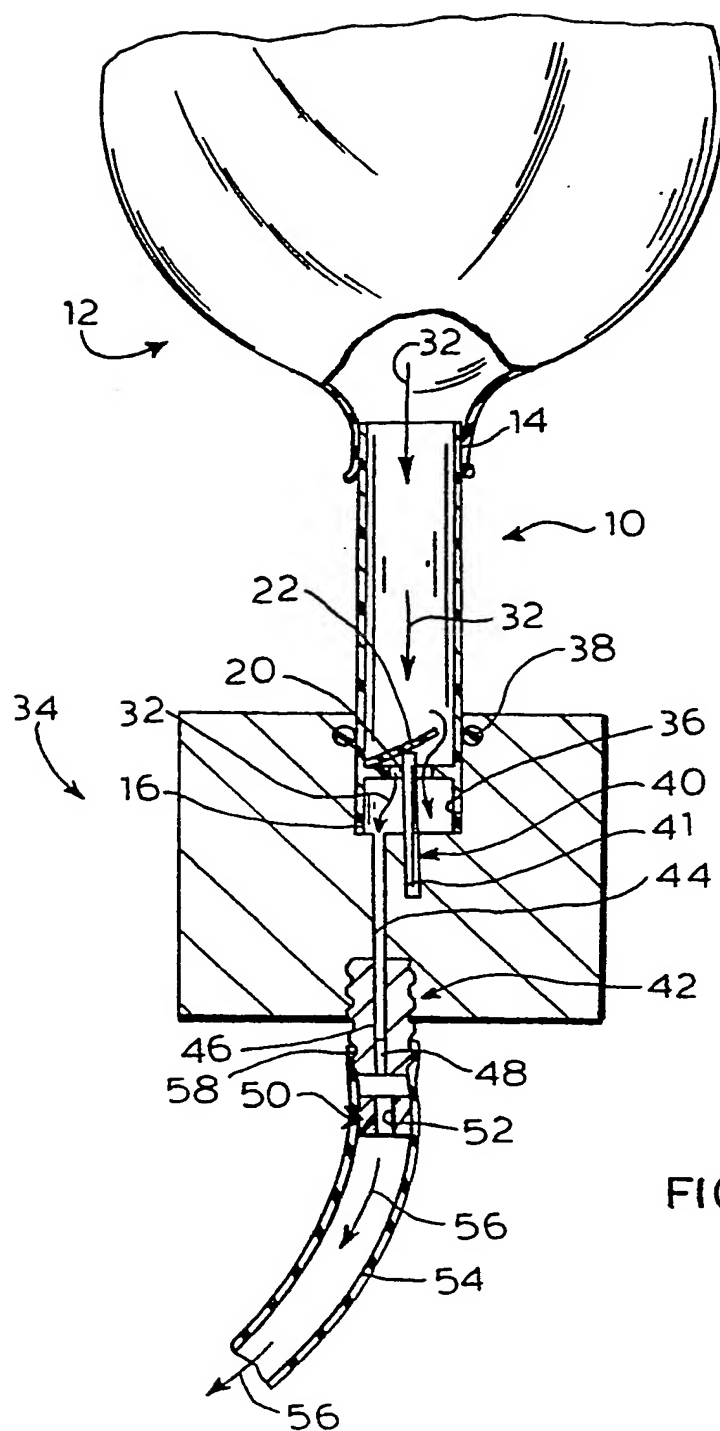
7. An apparatus according to claim 6, further characterized in that the breath sample body inlet is tubular; and the sample collector body inlet is a bore (36) having a diameter of a size for receiving the breath sample collector body inlet in sealing engagement.

8. An apparatus according to claim 6 or 7, further characterized in that the abutment means (40) is an elongated rod fixed in the sample collector body inlet; with the rod extending into the breath sample body inlet for engaging and opening the one-way valve means when the breath sample body inlet is received into the sample collector body inlet.

9. An apparatus according to claim 6, 7 or 8, further characterized by an O-ring (38) in the inlet bore of the sample collector body for enhancing sealing engagement with the breath sample body.



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# EUROPEAN SEARCH REPORT

0127259

Application number

EP 84 30 1149

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 7)
Y	US-A-3 196 689 (M.R. FORRESTER et al.) * Column 2, lines 41-65; column 5, lines 29-46; figures 1, 2, 11 *	1-3	A 61 B 5/08 G 01 N 1/00
A		4, 7	
Y	US-A-3 420 224 (A.F. FARR) * Column 1, lines 13-22, 44-57; column 2, line 41; column 3, line 30; figures 1, 2 *	1-3	
A		5	
A	US-A-3 635 214 (W.A. RAND et al.) * Abstract; column 4, lines 13-20, 45-56; figures 2, 5 *	2, 7, 9	TECHNICAL FIELDS SEARCHED (Int. Cl. 7)
A	GB-A-1 371 300 (MEEDA SCIENTIFIC INSTRUMENTATION LTD.) * Page 1, lines 72-80; figure 1 *	2, 3	A 61 B G 01 N
A	US-A-4 291 704 (T.L. PETTY et al.) * Abstract; column 2, line 27-35; column 3, lines 3-38; column 4, lines 36-53; figures 1-5 *	1, 4-7	
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 28-08-1984	Examiner RIEB K.D.
CATEGORY OF CITED DOCUMENTS		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document			



DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int. Cl. 7)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
A	FR-A-1 209 769 (SOC. D'ELECTROCHIMIE, D'ELECTROMETALLURGIE ET DES ACIERIES ELECTRIQUES D'UGINE) * Page 1, left-hand column, lines 8-12; page 2, left-hand column, line 1 - right-hand column, line 11; figure 2 *	6, 8	
A	DE-A-2 759 119 (SYBRON CORP.) * Page 6, lines 2-11; page 6, line 24 - page 7, line 3; page 7, line 21 - page 9, line 19; fig- ures 1-3 *	6, 8	
The present search report has been drawn up for all claims			TECHNICAL FIELDS SEARCHED (Int. Cl. 7)
Place of search THE HAGUE		Date of completion of the search 28-08-1984	Examiner RIEB K.D.
<p><b>CATEGORY OF CITED DOCUMENTS</b></p> <p>X : particularly relevant if taken alone  Y : particularly relevant if combined with another document of the same category  A : technological background  O : non-written disclosure  P : intermediate document</p> <p>T : theory or principle underlying the invention  E : earlier patent document, but published on, or after the filing date  D : document cited in the application  L : document cited for other reasons  &amp; : member of the same patent family, corresponding document</p>			